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PATENT

Attorney Docket No.: A-14

Commissioner for Patents,
P.O. Box 1450
Alexandria, VA 22313-1450

On Dec. 18, 2003

By Michelle Nicely
Michelle Nicely

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:)
)
PHILIP E. EGGERS et al.) Examiner: Lee Cohen
)
Application No.: 09/709,035) Art Unit: 3739
)
Filed: November 8, 2000)
)
For: SYSTEMS AND METHODS FOR TISSUE)
ABLATION AND RESECTION)

COMMUNICATION

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

The following information is being brought to the Examiner's attention.

I. LITIGATION ACTIVITY

Smith & Nephew litigation

On July 25, 2001, ArthroCare Corporation commenced an action in the United States District Court for the District of Delaware against Smith & Nephew, Inc. ("Smith & Nephew") for infringement of U.S. Patent Nos. 5,697,536 ("the '536 Patent"), 5,697,882 ("the '882 Patent") and 6,224,592 ("the '592 Patent"). That action was assigned Civil Action No. 01-504-SLR (the "*Smith & Nephew* litigation"). The *Smith & Nephew* litigation proceeded to trial commencing on April 30, 2003. On May 12, 2003, the jury returned a verdict in favor of ArthroCare on infringement and validity issues with

respect to all three patents. A copy of the jury's verdict, dated May 12, 2003, is enclosed. Thereafter, on June 20, 2003, the Court entered judgment on the jury's verdict. A copy of the judgment is enclosed.

Numerous papers were filed with the Court during the *Smith & Nephew* litigation. The official docket kept by the clerk of the Delaware District Court, which is 43 pages long, is enclosed. The files holding the documents corresponding to the docket entries on the official docket span approximately eight linear feet of shelving space. Applicant is enclosing herewith the following documents from the *Smith & Nephew* litigation which show Smith & Nephew's and Applicant's primary arguments relating to issues of validity and enforceability:

1. Smith & Nephew's Supplemental Responses to Plaintiff ArthroCare's Interrogatories Nos. 4 And 5, dated December 19, 2001;
2. Smith & Nephew's Supplemental Invalidity And Infringement Contentions, served March 29, 2002¹;
3. Smith & Nephew's Supplemental Invalidity Contentions, served June 3, 2002;
4. Smith & Nephew's Supplemental Invalidity Contentions, served September 10, 2002;
5. Smith & Nephew's Supplemental Invalidity Contentions, served October 9, 2002;
6. ArthroCare's Validity Contentions, served October 15, 2002;
7. Memorandum Order Re: Claim Construction, filed April 9, 2003;
8. Smith & Nephew's Notice Pursuant To 35 U.S.C. § 282;
9. Trial Testimony Of Smith & Nephew's Expert Dr. Kim Manwaring on May 6, 2003;
10. Trial Testimony Of Smith & Nephew's Expert Dr. Kenneth Taylor on May 7 & 8, 2003;
11. Jury Verdict, dated May 12, 2003;
12. Judgment In A Civil Case, filed June 20, 2003;
13. Smith & Nephew's Opening Brief In Support Of Its Inequitable Conduct Case, filed June 9, 2003;
14. Smith & Nephew's Opening Brief In Support Of Its Rule 50(b) Motion For Judgment As A Matter Of Law, filed June 30, 2003;
15. ArthroCare's Corrected Answering Brief In Opposition To Smith & Nephew's Opening Brief In Support Of Its Inequitable Conduct Case, filed July 11, 2003²;

1. Smith & Nephew marked its infringement contentions "Highly Confidential – Attorneys' Eyes Only" under the protective order. Accordingly, Applicant has secured redacted pages that omit Smith & Nephew's infringement contentions from this document.

² Smith & Nephew's Reply Brief In Support Of Its Inequitable Conduct Case, dated July 24, 2003, was filed under seal by Smith & Nephew. If the Examiner requests a copy, Applicant will contact Smith & Nephew in an attempt to secure an agreement by which the brief can be disclosed.

16. ArthroCare's Answering Brief In Opposition To Smith & Nephew's Rule 50(b) Motion For Judgment As A Matter Of Law, filed July 30, 2003;
17. Smith & Nephew's Reply Brief In Support Of Its Rule 50(b) Motion For Judgment As A Matter Of Law, filed August 14, 2003.

In addition to the above-listed materials, there are numerous other papers that were filed with the Court or served in connection with the *Smith & Nephew* litigation that relate to invalidity or enforceability issues. These include, for example, the expert reports of Dr. S. Nahum Goldberg (ArthroCare's expert on infringement and validity), Dr. Kenneth Taylor (Smith & Nephew's expert on infringement and invalidity), Dr. Kim Manwaring (Smith & Nephew's expert on invalidity), Dr. Michael Choti (Smith & Nephew's expert on infringement and invalidity), Charles Van Horn (ArthroCare's expert on patent prosecution issues), and Ronald Panitch (Smith & Nephew's expert on patent prosecution issues).

Smith & Nephew also served a paper purportedly prepared by Dr. Brian Skromme of Arizona State University related to the validity of the '882 patent. Moreover, the parties filed motions for summary judgment on issues pertaining to the validity of the patents-in-suit. The briefs in support of and opposition to these motions are listed as docket numbers 247, 248, 257, 258, 261, 262, 280, 283, 292, 298, 300, and 302 on the official docket that ArthroCare has enclosed. Smith & Nephew also produced a declaration from Eberhard Roos, the named inventor on U.S. Patent No. 4,116,198 and co-author of the Roos and Elsasser article ("Über ein Instrument zur leckstromfreien transurethralen Resektion"), both of which were references asserted in the Smith & Nephew litigation. There also are many trial exhibits. In addition, pre-trial depositions were taken of several witnesses regarding validity and enforceability issues, including depositions of Dr. Goldberg, Dr. Taylor, Dr. Manwaring, Dr. Choti, Mr. Van Horn, and Mr. Panitch. A list of the depositions taken in the *Smith & Nephew* litigation is set forth below:

1. John Tighe, taken September 18, 2002 and November 8, 2002 (ArthroCare employee, fact witness);
2. Diane DeLucia, taken September 19, 2002 (Smith & Nephew employee, fact witness);
3. John Raffle, taken September 19, 2002 and November 11, 2002 (ArthroCare employee and patent attorney, fact witness);
4. James Heslin, taken September 24, 2002 (patent attorney, fact witness);
5. Fernando Sanchez, taken September 24, 2002 (ArthroCare employee, fact witness);
6. Duane Marion, taken September 28, 2002 (former Smith & Nephew employee, fact witness);
7. John Graf, taken October 1, 2002 (Smith & Nephew employee, fact witness);

8. Hira Tahpliyal, taken October 1, 2003 and November 14, 2002 (co-inventor of patents-in-suit, fact witness);
9. Jim Pacek, taken October 3, 2002 and November 7, 2002 (ArthroCare employee, fact witness);
10. John Konsin, taken October 3, 2002 (Smith & Nephew employee, fact witness);
11. Jean Woloszko, taken October 3, 2002 (ArthroCare employee, fact witness);
12. Andrew Eggers, taken October 4, 2002 (employee of Eggers & Associates (owned by Philip E. Eggers, co-inventor of patents-in-suit), fact witness);
13. Bruce Prothro, taken October 4, 2002 (ArthroCare employee, fact witness);
14. Kara Weldon, taken October 5, 2002 (current or former Smith & Nephew employee, fact witness);
15. David Balford, taken October 5, 2002 (Smith & Nephew employee, fact witness);
16. Allen Weinstein, taken October 8, 2002 (ArthroCare employee, fact witness);
17. Christine Hanni, taken October 10, 2002 (former ArthroCare employee, fact witness);
18. Linda Guthrie, taken October 11, 2002 (Smith & Nephew employee, fact witness);
19. Michael Baker, taken October 11, 2002 (ArthroCare CEO, fact witness);
20. Kate Knudsen, taken October 11, 2002 and November 7, 2002 (Smith & Nephew employee, fact witness);
21. Sally Maher, taken October 11, 2002 (Smith & Nephew employee, fact witness);
22. Ron Sparks, taken October 11, 2002 (Smith & Nephew CEO, fact witness);
23. Philip E. Eggers, taken October 15 and 29, 2002, November 13, 2002, and April 30, 2003 (co-inventor of patents-in-suit, fact witness);
24. Tom Ross, taken October 15, 2002 (current or former employee of Oratec Interventions, Inc. (acquired by Smith & Nephew), fact witness);
25. Jack Cordes, taken October 15, 2002 (former employee of Eggers & Associates, fact witness);
26. Michael Long, taken October 29, 2002 (former Smith & Nephew employee, fact witness);
27. Joan McCreary, taken October 30, 2002 (Smith & Nephew employee, fact witness);
28. Todd Plevinsky, taken October 31, 2002 (former Smith & Nephew employee, fact witness);
29. Karen Drucker, taken November 1 and 14, 2002 (Smith & Nephew employee, fact witness);
30. Allen Gannon, taken November 1, 2002 (Smith & Nephew employee, fact witness);
31. Jim Pacek, taken November 7, 2002 (ArthroCare employee, fact witness);
32. Tim Crabtree, taken November 7, 2002 (former Smith & Nephew employee, fact witness);
33. John Konsin, taken November 7, 2002 (Smith & Nephew employee, fact witness);

34. Jason Krieser, taken November 13, 2003 (Smith & Nephew employee, fact witness);
35. Dr. Kim Manwaring, taken March 20, 2003 (Smith & Nephew expert witness);
36. Dr. Eliot Leitman, taken March 25, 2003 (ArthroCare expert witness);
37. Dr. Kenneth Taylor, taken March 27 and 28, 2003 (Smith & Nephew expert witness);
38. Dr. S. Nahum Goldberg, taken March 27 and 28, 2003 (ArthroCare expert witness);
39. Ronald Panitch, taken March 28, 2003 (Smith & Nephew expert witness);
40. Dr. Michael Choti, taken March 30, 2003 (Smith & Nephew expert witness);
41. Charles Van Horn, taken April 3, 2003 (ArthroCare expert witness);
42. Creighton Hoffman, taken April 4, 2003 (ArthroCare expert witness);
43. Brian Napper, taken April 17, 2003 (Smith & Nephew expert witness);
44. Warren Heim, taken April 22, 2003 (consultant to Smith & Nephew, fact witness).

Smith & Nephew designated many of the materials from the *Smith & Nephew* litigation as confidential pursuant to the protective order in that case. Without admitting the materiality or relevance of the foregoing materials, Applicant will submit any or all of the foregoing materials to the Examiner for consideration or, if the Examiner requests materials that have been filed under seal or designated confidential pursuant to the protective order, Applicant will contact Smith & Nephew in an attempt to secure an agreement by which such materials can be disclosed.

II. REEXAMINATION

A. The '536 Patent

On December 23, 1999, an *Ex Parte* Reexamination Request ("Request") for the '536 Patent was filed with the PTO. Applicant has enclosed a copy of the file history for the '536 Reexamination with this Information Disclosure Statement. The Request sought reexamination of claims 1-3, 14, 16, 22, 27, 30, 33, 38, 41-48, 55, 57, 60, and 63 of the '536 Patent in light of U.S. Patent 4,116,198 ("the Roos '198"). The PTO granted the Request on October 27, 2000.

On November 15, 2002, the PTO mailed an Office Action. The Office Action is divided into two sections. Section I sets forth the conclusion of the examiner and a board of primary examiners that "the Roos '198 does not anticipate or render obvious any of the independent claims of record." *See* November 15, 2002 Office Action at 3. Section II contains a rejection of claims 1-64 of the '536 Patent as anticipated under 35 U.S.C. § 102(b) and obvious under 35 U.S.C. § 103 in light of certain references

identified in an Information Disclosure Statement filed by Applicant on June 19, 2002. On December 19, 2002, Applicant submitted a Response to the Office Action.

On March 14, 2003, the PTO issued a Notice of Intent to Issue *Ex Parte* Reexamination Certificate ("NIRC"). The NIRC states that "the examiner of record concurs with the arguments presented by patent Applicant on paper number 15. Accordingly, it is concluded that claims 1-64 are allowable over the prior art of record." See NIRC at 2. A Reexamination Certificate issued on June 10, 2003.

Additionally, on April 9, 2003, another *Ex Parte* Reexamination Request for the '536 Patent was filed with the PTO. The Request sought reexamination of claims 1, 2, 5, 9, 14, 15, 25, 26, 28, 30-33, 36, 38, 40, 42-47, 49, 53, 55, 56, 58, 59, 61, and 63 of the '536 Patent in light of the Roos '198; Elasser and Roos, "Uber ein Instrument zur leckstromfreien transurethralen resection," Medizinal-Markt/Acto Medico-technica, Vol. 24, No. 4/1976, pp. 129-134 ("the Elasser and Roos article"); U.S. Patent Nos. 4,805,616; 4,674,499; 4,381,007; 5,217,459; and 5,007,908. The PTO granted the Request on June 30, 2003. It has been assigned Reexamination No. 90/006,597.

B. The '882 Patent

On April 18, 2003, an *Ex Parte* Reexamination Request for the '882 Patent was filed with the PTO. The Request sought reexamination of claims 1, 13, 17, 18, 24, 26, 28, 29, 48 and 54 of the '882 Patent in light of U.S. Patent Nos. 5,122,138; 5,007,908; and Slager et al., "Vaporization Of Atherosclerotic Plaques By Spark Erosion," JACC Vol. 5, No. 6, June 1985:1382-6 ("the Slager Article"). The PTO granted the Request on July 1, 2003. It has been assigned Reexamination No. 90/006,607.

C. The '592 Patent

On April 21, 2003, an *Ex Parte* Reexamination Request for the '592 Patent was filed with the PTO. The Request sought reexamination of claims 1, 3, 4, 9, 11, 21, 23, 26, 27, 30, 32 and 42 of the '592 Patent in light of the Roos '198; the Elasser and Roos article; U.S. Pat. Nos. 4,381,007 to Doss; and the Slager Article. The PTO granted the Request on July 7, 2003. It has been assigned Reexamination No. 90/006,611.

Should the Examiner desire copies of any of the documents filed in connection with the above reexaminations Applicant will submit them upon a request to do so in writing from the Examiner.

III. CO-PENDING PATENT APPLICATIONS

The following is a list of co-pending applications:

Application No.	Filing Date
09/293,231	16-Apr-1999
09/314,247	18-May-1999
09/338,842	23-Jun-1999
09/347,390	06-Jul-1999
09/354,835	16-Jul-1999
09/360,075	23-Jul-1999
09/372,454	11-Aug-1999
09/457,201	06-Dec-1999
09/501,327	09-Feb-2000
09/512,742	24-Feb-2000
09/539,147	30-Mar-2000
09/562,496	01-May-2000
09/562,650	01-May-2000
09/586,295	02-Jun-2000
09/679,394	03-Oct-2000
09/708,962	08-Nov-2000
09/709,035	08-Nov-2000
09/735,426	12-Dec-2000
09/747,311	20-Dec-2000
09/758,403	10-Jan-2001
09/771,299	25-Jan-2001
09/780,745	09-Feb-2001
09/791,504	22-Feb-2001
09/796,094	28-Feb-2001
09/836,940	17-Apr-2001
09/839,427	20-Apr-2001
09/845,034	27-Apr-2001
09/848,843	03-May-2001
09/963,736	26-Sep-2001
10/057,412	25-Jan-2002
10/072,599	05-Feb-2002
10/082,017	20-Feb-2002
10/097,763	13-Mar-2002
10/119,925	09-Apr-2002
10/135,478	30-Apr-2002
10/139,117	03-May-2002
10/174,266	18-Jun-2002
10/175,472	18-Jun-2002
10/175,555	18-Jun-2002
10/187,733	27-Jun-2002

Application No.	Filing Date
10/261,969	30-Sep-2002
10/264,308	02-Oct-2002
10/288,227	04-Nov-2002
10/290,930	07-Nov-2002
10/291,213	08-Nov-2002
10/339,470	09-Jan-2003
10/367,608	13-Feb-2003
10/372,591	21-Feb-2003
10/374,411	25-Feb-2003
10/384,050	05-Mar-2003
10/389,159	13-Mar-2003
10/621,839	16-Jul-2003
10/437,260	13-May-2003
10/402,728	28-Mar-2003
10/392,529	20-Mar-2003
10/389,159	14-Mar-2003
10/613,609	02-Jul-2003
10/435,825	12-May-2003
10/613,115	03-Jul-2003
10/621,839	16-Jul-2003
10/661,118	12-Sep-2003
10/656,597	05-Sep-2003
10/682,600	09-Oct-2003
10/713,643	13-Nov-2003

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'R. Batt', written in a cursive style.

Richard R. Batt
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